DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JAN 17 2001

Re: Betaxon
Docket No. 00E-1402

The Honorable Q. Todd Dickinson
Director of U.S. Patent and Trademark Office
Commissioner for Patents
Box Pat. Ext.
Washington, D.C. 20231

Dear Director Dickinson:

This is in regard to the application for patent term extension for U.S. Patent No. 4,911,920 filed by Alcon Laboratories under 35 U.S.C. § 156. The human drug product claimed by the patent is Betaxon (levobetaxolol), which was assigned new drug application (NDA) No. 21,114.

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). Our records also indicate that it represents the first permitted commercial marketing or use of the product, as defined under 35 U.S.C. § 156(f)(1), and interpreted by the courts in *Glaxo Operations UK Ltd. v. Quigg*, 706 F. Supp. 1224 (E.D. Va. 1989), *aff'd*, 894 F. 2d 392 (Fed. Cir. 1990).

Under 35 U.S.C. § 156(d)(1), the patent term extension must be submitted within 60 days of the product's approval, or on the next business day after the sixtieth day if the sixtieth day falls on a weekend or holiday. In the case of Betaxon, the NDA was approved on February 23, 2000. The sixtieth day after approval fell on Sunday, April 23, 2000, so the deadline for submission of the patent term extension application was the next business day, April 24, 2000. However, the patent term extension application was not submitted until April 26, 2000, which is not timely within the meaning of 35 U.S.C. § 156(d)(1).

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. § 156(d)(2)(A) we will then determine the applicable regulatory review period, publish the determination in the *Federal Register*, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Sally Yeager
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